IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF MASSACHUSETTS
Worcester Division

DARLENE BERNARD,	§	
Plaintiff	§	
	§	
vs.	§	**COMPLAINT AND JURY DEMAND**
	§	
MERCK & COMPANY, INC., and PFIZER, INC.,	§	**Civil Action No.**
Defendants.	§	

NOW COMES the Plaintiff, Darlene Bernard, and by and through her attorneys hereby brings this cause of action against the defendants, Merck and Company, Inc., (hereinafter, "Merck") and Pfizer, Inc. (hereinafter, Pfizer).

THE PARTIES

1. Plaintiff, Darlene Bernard, is a resident of Worcester County, Massachusetts and at all relevant times was a resident of the state of Massachusetts. Plaintiff brings this action to recover for personal injuries she sustained as a result of ingestion of and exposure to Defendants' pharmaceutical drug products.

2. Defendant, Merck, is a New Jersey corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey, 08889-0100. Merck is a foreign corporation doing business in the State of Massachusetts and maintains an office and/or other facilities within this Judicial District. At all relevant times, Merck manufactured, tested, distributed, marketed, and/or sold the drug rofecoxib throughout the United States and in Massachusetts, under the brand name Vioxx for the treatment of pain.

3. Defendant, Pfizer is a New York corporation with its principal place of business at 235 East 42nd Street, New York, New York, 10017. Pfizer is a foreign corporation doing business in the

State of Massachusetts and maintains an office and/or other facilities within this Judicial District. At all relevant times, Pfizer manufactured, tested, distributed, marketed, and/or sold the drug celecoxib throughout the United States and in Massachusetts, under the brand name Celebrex, respectively, for the treatment of pain.

JURISDICTION AND VENUE

4. This court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (diversity jurisdiction) because the amount in controversy exceeds $75,000 exclusive of interest and costs, and because this is an action by an individual Plaintiff who is a citizen of a different state from the Defendants. Plaintiff's cause of action arises out of the Defendants (1) transacting business in Massachusetts; (2) contracting to supply and/or sell goods in Massachusetts; (3) doing or causing a tortious act to be done in Massachusetts; and/or (4) causing the consequence of a tortious act to occur within Massachusetts, and the Defendants do, or solicit business or engage in a persistent course of conduct or derives substantial revenue from the sale of goods in Massachusetts.

5. Venue is proper pursuant to 28 U.S.C. §§ 1391(a) and 1391(c).

INTRODUCTION

6. This action arises from the sale and distribution of Vioxx (rofecoxib), and Celebrex (celecoxib). Vioxx is the brand name used by Defendant Merck to market and distribute rofecoxib. Celebrex is the brand name used by Pfizer to market and distribute celecoxib. Vioxx and Celebrex have been proven to cause adverse cardiovascular effects including, but not limited to, heart attack and stroke.

7. During all relevant times herein, Defendants Merck and Pfizer have been engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing,

producing, processing, inspecting, distributing, marketing, labeling, promoting, packaging and advertising the prescription drugs known as Vioxx and Celebrex for ingestion by consumers. Vioxx was manufactured, sold, designed, supplied, prescribed, distributed, marketed and processed by Defendant Merck, who was at all times acting through its servants, employees, representatives and agents, who placed Vioxx in the market to be purchased and used by the public. Celebrex was manufactured, sold, designed, supplied, prescribed, distributed, marketed and processed by Defendant Pfizer, who was at all times acting through its servants, employees, representatives and agents, who placed Celebrex in the market to be purchased and used by the public.

8. Defendants Merck and Pfizer participated in, authorized and directed the production and promotion of their respective drugs when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of their respective drugs and thereby actively participated in the tortuous conduct which resulted in the injuries suffered by the Plaintiff. The drugs ingested by Plaintiff combined to cause an indivisible injury to Plaintiff

9. Vioxx and Celebrex are members of a class of drugs known as "NSAIDs" (non-steroidal anti-inflammatory drug) but, more specifically, contains cycloosygenase 2 ("COX-2") inhibitory properties. Generally, NSAIDs prevent the formation of fatty acid cyclooxygenases, of which there are two known types ("COX-1" and "COX-2").

10. Merck obtained FDA approval for Vioxx on May 20, 1999, for treatment of dysmenorrheal (painful menstrual cramps), management of acute pain in adults, and relief for the symptoms of osteoarthritis.

11. Merck obtained Vioxx's FDA approval for marketing, sale, and distribution based on inaccurate, false, and misleading information, contained in the New Drug Application. Subsequent to FDA approval, Defendant advertised and marketed Vioxx as safe and effective pain relief medication throughout the United States.

12. Plaintiff, Darlene Bernard, received prescriptions for Celebrex and took the drug as prescribed by a medical professional and suffered a heart attack. Plaintiff's use of Celebrex was a direct, producing and proximate cause of her injuries. Subsequently, Plaintiff received prescriptions for Vioxx and suffered a second heart attack. Plaintiff's use of Vioxx was a direct, producing and proximate cause of her injuries.

13. At all relevant times, Plaintiff was ignorant of the dangerous nature of Vioxx and Celebrex, and the adverse cardiovascular effects that could occur because of consumption of and exposure to these drugs.

14. Through industry and medical studies, unknown to Plaintiff, Merck and Pfizer knew or should have known the adverse cardiovascular effects inherent in their products. Merck and Pfizer ignored or deliberately and fraudulently concealed the increased cardiovascular risk in order to sell their products, avoid the costs of safety precautions, and avoid litigation by people injured by the drugs. The conduct of Merck and Pfizer constitutes gross negligence and demonstrates a reckless, willful and wanton disregard for the rights and safety of others justifying punitive damages against each of these Defendants.

FACTUAL BACKGROUND

VIOXX'S PRE-APPROVAL:

15. In the mid to late 1990's, Defendant Merck faced the loss of patent protection of its top selling and most profitable drugs. In 1996, Merck began plans for a proposed study to prove

Vioxx was gentler on the stomach than older painkillers.

16. In need of a new blockbuster drug, Merck pushed forward with plans for the study and ignored a November 1996 memo from a top Merck official that stated, "there is a substantial chance that significantly higher rates" of cardiovascular problems would result form Vioxx. Further, Merck concealed or ignored a February 1997 e-mail regarding the study from another Merck official that revealed, "you will get more thrombotic events" or blood clots unless the Vioxx receiving patients in the study also received aspirin.

17. In response to the February 1997 e-mail, Merck Vice President for Clinical Research, Dr. Alise Reicin, wrote, "the possibility of increased cardiovascular risk (from Vioxx) is of great concern." To remedy this problem and conceal Vioxx's adverse cardiovascular effects, Dr. Reicin proposed people with risk of cardiovascular problems be kept out of the study to ensure that cardiovascular effects would not be evident. Despite its internal knowledge and information relating to cardiovascular-related adverse health effects, Merck forged ahead, aggressively promoting and marketing Vioxx as safe and effective for persons such as Plaintiff in efforts to obtain FDA approval.

18. While it is not clear as to what became of this 1996-97 proposed study, it is clear that Merck concealed its knowledge of the serious cardiovascular risks associated with Vioxx because a successful launch of Vioxx was viewed as financially critical for Merck to retain its current market share and to sustain stock value. Vioxx's chief competing drug Celebrex (Celecoxib) was placed into the market by Merck's competitors, Pharmacia and Pfizer, three months prior to the launch of Vioxx.

19. Merck's disclosure of the safety concerns over hypertension, thrombosis, edema and/or cardiovascular events would have drastically impacted Merck's positioning in the market.

VIOXX'S POST-APPROVAL:

20. Merck intentionally and knowingly chose to market Vioxx, despite its pre-FDA-approval knowledge, its knowledge at product launch, and its post-FDA-approval data thereafter, that the use of Vioxx carried significant risk factors. These risks were further realized in adverse event reports, in clinical trials where such events were adjudicated by primary investigators with Merck's assistance, and in numerous studies shortly after market launch, which showed statistically significant increases in adverse cardiovascular events among Vioxx users.

21. In early 1999, Merck started the 8,000 person VIGOR (Vioxx Gastrointestinal Outcomes Research study) to prove the drug's gastrointestinal safety benefits. The March 2000 VIGOR results revealed precisely what the above discussed internal Merck documents anticipated - a significant increase in the number of blood-clot related problems among Vioxx users. The heart attack rate in the Vioxx group was five times that of the other group taking naproxen.

22. Merck research chief Dr. Scolnick confessed that there was an inherent risk in Vioxx, and stated in an internal March 9, 2000 e-mail, that cardiovascular events are "clearly there" and called it a "shame" that it is mechanism (Vioxx) based. Dr. Scolnick recognized that the cardiovascular effects could not have come from naproxen's protective effect. Merck's research chief wrote that like all Merck's big selling drugs, Vioxx too had side effects but assured Merck that it would "do well."

23. In March of 2000, however, Merck issued a news release that the trial results' cardiovascular findings were "consistent with" naproxen's favorable effects. To date, and not surprisingly, the only studies to report a protective cardiovascular effect with naproxen are those funded and assisted by Merck. Contrary to the studies funded by Merck, a number of independent studies have reported no reduction in risk with naproxen use. In fact, an FDA researcher recently published a report that contradicts Merck's position and holds naproxen is not

protective against coronary heart disease and, if anything, actually confers an increase in risk. Merck intentionally and knowingly made false assertions relating to the VIGOR trial with a blatant disregard for the public welfare to conceal Vioxx's adverse cardiovascular effects in order to profit, maintain, and gain market position.

24. Merck repeatedly and purposefully downplayed, understated, and concealed the health hazards of Vioxx evident in the VIGOR study. In April of 2000, Merck issued its response to the VIGOR results in a news release headlined, "Merck confirms favorable cardiovascular safety profile of Vioxx." This and other similar Merck-generated news releases were strategically designed and calculated to deceive and mislead the public about Vioxx's serious adverse effects.

25. In June of 2000, industry sponsored studies presented at the European United League Against Rheumatism (EULAR), an organization in which Merck is a member and corporate sponsor, showed that Vioxx use resulted in statistically significant increases in hypertension and myocardial infarction. Merck did nothing to publish these studies, which were again reported and denied by Merck as to the hypertension problems in the official publication of the American Pharmaceutical Association, Pharmacy, Today, Spin War Aside, Lessons Emerge From COX_2 Trials, in August 2000, page 3.

26. Merck continuously and systematically denied the adverse health effects associated with Vioxx while at the same time reaping the profits obtained through the non-disclosure. Merck engaged in an aggressive and expansive advertising and sampling program and gained continued increases in market share. Merck spent over $160 million on direct-to-consumer television advertising on Vioxx in 2000. The resultant effect for this multi-million dollar advertising blitz combined with Merck's concealing and failing to reveal and warn of the risks was more that $2 billion in profits in the year 2000 alone to Merck and an approximately twenty-three percent market share.

27. Merck's multi-million dollar advertising campaign created the image and impression and belief that the use of Vioxx was safe for adults, had fewer side effects and adverse reactions than other pain relief medications and would not interfere with daily life, even though Merck knew these representations to be false. The advertisements, combined with their other promotional literature, audio conferences, professional meetings and press releases, deceived potential consumers by relaying positive information, including testimonials from satisfied consumers. Merck manipulated the statistics to suggest widespread acceptability and safety of the product, while intentionally understating the known adverse and serious risks associated with the use of Vioxx. Merck's advertising and marketing campaign conveyed the false impression that Vioxx was a drug of first choice when it should not have been.

28. In the fall of 2000, Merck again sunk to new levels in their efforts to conceal information by employing a barrage of ruthless intimidation and retaliation tactics against those who spoke out regarding Vioxx's adverse effects. In October of that year, Merck official Louis Sherwood contacted James Fries, MD, a Stanford University Medical Professor, to inform him that if his "irresponsibly anti-Merck and specifically anti-Vioxx" lectures did not stop, that he would "flame out." Dr. Fries responded in a letter to Merck Chief Executive Gilmartin stating, "that Merck had crossed (an ethical) line, that you can't go across." Dr. Fries also explained that several other top medical schools complained of "a consistent pattern of intimidation by Merck" on Vioxx.

29. Lee Simon, MD, a rheumatologist at Beth Israel Deaconess Medical Center in Boston, reported being the victim of similar intimidation tactics when he publicly mentioned data suggesting that Vioxx might be associated with a risk of high blood pressure and swelling. Dr. Simon was "shocked that a phone call was made" to his superior to complain that his lectures were slanted against Vioxx; Dr. Simon rightfully believed that Merck was "attempting to

suppress discussion about this data.

30. On November of 2000, Merck caused the publication of a study in the New England Journal of Medicine and knowingly downplayed and/or withheld from this publication the severity of cardiovascular risks associated with Vioxx consumption over naproxen consumption. The article simply failed to provide critical information about Vioxx related cardiovascular complications such as stroke or blood clots.

31. The year 2001 proved to be more of the same; huge efforts by Merck to conceal and hide Vioxx's adverse effects from the public and, in turn, Merck reaped huge profits. In 2001, Merck spent $135 million to promote the drug in the United States alone; Merck was rewarded with $2.6 billion in revenue making Vioxx the world's tenth best selling medicine.

32. In February of 2001, when the FDA received the results of the VIGOR study, the FDA wanted to highlight the cardiovascular risk prominently on Vioxx's label. Merck resisted and fought to maintain its warning/caution free label, which remained unchanged until April 2002 when Merck and FDA reached a compromise. Merck's relentless and aggressive efforts to keep the public in the dark enabled them to maintain market position and profits for yet another year, all at the expense of persons such as Plaintiff.

33. On or about August 29, 2001, the Journal of the American Medical Association, ("JAMA") published a peer reviewed human epidemiologic study by the Cleveland Clinic Foundation that showed the risk of a thrombotic cardiovascular event or myocardial infarction among Vioxx users in Merck's trials at a 95% confidence interval ranged from 2.2 for event-free survival analysis, 2.39 compared to naproxen users, and 4.89 for developing serious cardiovascular events among aspirin patients. See *Mukherjee, D., et al., Risk of Cardiovascular Events Associated With Selective Cox-2 Inhibitors,* JAMA. 286:8, 954-959, Aug. 22/29, 2001. In addition, the annualized myocardial infarction rates for Vioxx users compared to placebo

revealed a statistically significant increase among Vioxx users. *Id.*

34. The JAMA study authors set forth the theory that "by decreasing PG12 production [Vioxx] may tip the natural balance between pro-thrombotic thromboxane A2 and anti-thrombotic PG12, potentially leading to an increase in thrombotic events." *Id.* At 957. In a follow-up peer-reviewed study reported in the Journal of the American College of Cardiology on or about February 6, 2002, Dr. Richard J. Bing conducted scientific testing and confirmed that the COX-2 inhibitor "tips the balance of prostacyclin/thromboxane in favor of thromboxane, leading to increased vascular thrombotic events." Bing, R., & Lomnicka, M., *Why Do Cylo-Oxygenase-2 Inhibitors Cause Cardiovascular Events?, J.A.C.C.,* 39:3, Feb. 6, 2002. This biological plausibility is further supported by studies completed at the University of Pennsylvania. Cheng, T., et al., *Role of Prostacyclin in the Cardiovascular Response to Thromboxane A2,* Journal of Science, V. 296: 539-541, Apr. 19, 2002.

35. The JAMA study's release was followed by a relentless series of publications and peer reviewed literature by Merck employees and consultants again setting forth the blatantly false theory that naproxen had anti-thrombotic effects which accounted for the appearance of cardiovascular risk among Vioxx users. Again, the only studies to ever make this assertion were funded by Merck. Merck's theory has been debunked by numerous medical journals and, moreover, the FDA recently stated that this theory could not be further from the truth.

36. In mid-September 2001, Merck received a third warning letter from the FDA stating, in part, that Defendant's promotional activities are "false, lacking in fair balance, or otherwise misleading in violation of the Federal Food, Drug and Cosmetic Act (the Act) and applicable regulations." The FDA stated that Merck's promotional campaign "minimizes the potentially serious cardiovascular findings" from a Vioxx study and "misrepresents the safety profile on

Vioxx." As to a Merck press release, dated May 22, 2001, the FDA wrote "your claim in the press release that Vioxx has a `favorable safety profile' is simply incomprehensible, given the rate of MI (myocardial infarction) and serious cardiovascular events compared to naproxen. The implication that Vioxx's cardiovascular events were twice as frequent in the Vioxx group...as in the naproxen treatment group..."

37. Further, the FDA warning letter reprimanded Merck for setting forth this false theory relating to the VIGOR study that Naproxen had anti-thrombotic effects and went on to state that, "it is also possible that Vioxx has pro-thrombotic effects."

38. Nevertheless, Merck continued its course of action and continued its aggressive marketing campaign of Vioxx primarily through direct-to-consumer advertising.

39. In the midst of these adverse events, Merck took an offensive approach to marketing, providing all Vioxx field personnel with an "obstacle handling guide" to overcome doctors' objections to Vioxx relating to its cardiovascular problems. The training document was appropriately titled "Dodge Ball Vioxx." Merck's massive Vioxx sales force was instructed to avoid and "DODGE" serious, life threatening concerns of both health care professionals and the general public; Merck's corporate philosophy became one of "RUN" and "DODGE" as opposed to being that of "HONEST" and "TRUTHFUL."

40. In April 2002, Merck was required to place information about cardiovascular implications on its Vioxx labeling based on the results of the VIGOR study. In addition, Merck was required to place new label information that Vioxx 50 mg per day is not recommended for chronic use. These warnings were based on information that had been in Merck's possession since approximately January of 2000 at the latest and, as such, Merck did not meet its obligation to provide adequate "direction or warnings" as to the use of Vioxx within the meaning of Section 402 of the Restatement (Second) of Torts or otherwise. Nor did Merck fulfill its alleged

obligation to warn the prescribing health care provider of these risks.

41. Merck's internal documents reveal that Merck was set to begin a major cardiovascular study of Vioxx in 2002, but company officials abruptly dropped the project just before it was set to start. This proposed study, which became known as the VALOR trial, was set to begin in June of 2002. On March 13, 2002, however, Merck sent an e-mail to Merck employees worldwide that simply stated the trial was being put on hold and did not cite any details leading to the decision. Although Merck officials have publicly denied it, it is far more than a coincidence that their decision to cancel the trial fell amidst their negotiations with the FDA over the April 2002 cardiovascular warnings mentioned above. Merck's decision to cancel the VALOR trial is in concert with their corporate strategy to conceal information relating to Vioxx's adverse cardiovascular effects.

42. In the summer of 2002, Merck conducted its most inflammatory and aggressive measures via their intimidation and retaliation tactics to suppress and conceal speech and publicity relating to the adverse cardiovascular effects of Vioxx. Dr. Joan-Ramon Laporte of the Catalan Institute of Pharmacology in Barcelona, Spain, publicly criticized Merck's handling of Vioxx. Merck then had the audacity to send him a "rectification" that they insisted Dr. Laporte publish, which Dr. Laporte refused. Merck then filed suit against the doctor in Spanish Court demanding a public correction. In early 2004, the judge ruled that the publication accurately reflected the cardiovascular safety (or lack thereof) of Vioxx and ordered Merck to pay all court costs.

43. In October of 2002, the prestigious British medical journal, Lancet, published a study that analyzed the medical data of close to 300,000 people and determined that people who take Vioxx are almost twice at risk of developing heart disease, including heart attack. Lancet also concluded that there was no anti-thrombotic or protective effect of naproxen, effectively discounting Merck's theory. Again, Merck did not publicize or warn of these findings and instead

stuck to its same story for another two years. Merck continued to spend more than $100 million annually in direct-to-consumer advertising and expanded its distribution to more than eighty (80) countries.

44. On August 25, 2004, FDA researcher, Dr. David Graham, presented the results of a database analysis of 1.4 million patients at a medical conference that concluded Vioxx users are more likely to suffer a heart attack or sudden cardiac death than patients taking Celebrex. In fact, the report shows there is a 3.7-fold increase in risk compared with those taking Celebrex. With 92,791,000 prescriptions for Vioxx filed between 1999 and 2003, the FDA conservatively estimates an excess of 27,785 cases of AMI (Acute Myocardial Infarction) and SCD (Sudden Cardiac Death) for those years alone. Plaintiff is one of those 27,785 cases.

45. Merck was still not ready to concede the truth. On August 26, 2004, true to form, Merck attempted to minimize and downplay the adverse findings and authorized a press release refuting Dr. Graham's study entitle, "Merck stands behind the efficacy and overall safety and cardiovascular safety of Vioxx."

46. On September 23, 2004, Merck claims it had an epiphany. Merck had been sponsoring a small 2600 patient (APPROVe) study in order to gain additional FDA approval for Vioxx to treat the recurrence of colon polyps. The APPROVe study was stopped prematurely on the instruction of the Data and Safety Monitoring Board after the investigators found that after eighteen (18) months of treatment, patients taking Vioxx had twice the risk of a myocardial infarction compared with those receiving placebo. Merck alleges that this small study which was by no means intended to test for Vioxx's overall safety is what triggered the collapse of all their previous defenses. The results of the APPROVe study, combined with mounting pressure from the FDA, compelled Merck to finally acknowledge Vioxx's dangerous propensities. Merck then opted to back out rather than be forced out.

47. On September 30, 2004, Merck withdrew Vioxx from the U.S. market and the more than eighty (80) countries around the world. This came only after an estimated 80 million patients had taken the drug and Merck's annual sales had topped $2.5 billion. This represents the largest prescription drug withdrawal in history.

CAUSES OF ACTION AGAINST MERCK

48. Critics have described the rise and fall of Vioxx as a cautionary tale of masterful public relations and aggressive marketing. At all times relevant to this litigation, Defendant Merck had a significant market share based upon claims of Vioxx's efficacy, a very aggressive marketing program that included financial incentives to sales teams, infusion of some 700 new sales representatives, and a massive direct-to-consumer advertising and physician sampling program.

49. As a result of such marketing, Vioxx gained a significant market share in competition with Celebrex that Merck would not have gained if Merck had not suppressed and concealed information about Vioxx and/or made false representations of Vioxx's superiority and efficacy.

50. If Defendant had not engaged in this conduct, physicians would not have prescribed Vioxx and patients, like Plaintiff, would have switched from Vioxx to safer products or would have refrained wholly from any use of Vioxx.

51. From approximately 1999 through September 30, 2004, Defendant Merck continued to engage in a common scheme in marketing, distributing and/or selling Vioxx under the guise that it was safe and effective for persons such as Plaintiff before, during and after Plaintiff experienced this confirmed adverse cardiovascular event.

52. Plaintiff alleges that the marketing strategies, including, without limitation, the detail and sampling programs and direct-to-consumer advertising, of the Defendant Merck targeted Plaintiff to purchase Vioxx. At the time the Defendant distributed, manufactured and marketed Vioxx, Defendant intended that Plaintiff and Plaintiff's health care professional would rely on the

marketing advertisements and product information propounded by Defendant.

53. The actions of Defendant, in failing to warn of the clear and present danger posed to others by the use of its drug Vioxx, in suppressing evidence relating to this danger, and in making deliberate and misleading misrepresentations of fact to minimize the danger or to mislead prescribers and patients as to the true risk, are the direct and proximate cause of Plaintiff's injuries. Plaintiff seeks compensation for the damages he has sustained relating to her past, present, and future physical pain and mental anguish, loss of earning capacity, disfigurement, physical impairment, and medical care expenses.

COUNT I
NEGLIGENCE AND GROSS NEGLIGENCE

54. Plaintiff re-alleges and incorporates the foregoing allegations.

55. Plaintiff would further show that at all times material hereto, the manufacture, sale, design, supply, distribution, or prescription of Vioxx with which Plaintiff came in contact, was under the exclusive control of the Defendant Merck, their agents, servants and employees, and that had the Defendant herein not been guilty of negligence, Plaintiff would not have sustained her injuries. Accordingly, Plaintiff is entitled to recover from Defendant Merck under the doctrine of *res ipsa loquitur*.

56. The law imposed a duty on Defendant Merck, as a manufacturer and marketer of pharmaceutical drugs, to exercise reasonable care in the design, marketing and warnings related to Vioxx and its risks. Defendant knew, or in the exercise of ordinary or reasonable care should have known, that the Vioxx it manufactured, sold, designed, supplied, distributed, promoted, or marketed was dangerous, unsafe, and highly harmful to Plaintiffs health, notwithstanding which:

a. Defendant negligently failed to design a reasonably safe product;

b. Defendant negligently placed Vioxx into the market;

c. Defendant negligently failed to remove Vioxx from the market;

d. Defendant negligently failed to fund and conduct medical and scientific studies to determine the risks of the overall safety of Vioxx, in the alternative, failed to heed the warnings and risks of Vioxx;

e. Defendant negligently failed to conduct sufficient testing on Vioxx that would have shown Vioxx had serious side effects, including, but not limited to the cardiovascular events described above;

f. Defendant negligently failed to conduct adequate post-marketing surveillance to determine the overall safety of Vioxx;

g. Defendant negligently failed to accurately disclose the results of their post-marketing surveillance to advise the Plaintiff, consumers, and the medical community of the aforementioned risks to individuals when the drugs were ingested;

h. Defendant negligently failed to investigate the adverse event reports relating to Vioxx;

i. Defendant negligently marketed its products;

j. Defendant negligently failed to provide Plaintiff with visible, understandable warnings that were adequate to convey and alert Plaintiff the severity of the risks and serious thrombotic cardiovascular side effects of Vioxx ingestion;

k. Defendant negligently failed to take any reasonable precautions or exercise reasonable care to warn Plaintiff of the potential risks and serious thrombotic and cardiovascular side effects of Vioxx ingestion;

l.. Defendant negligently failed to take any reasonable precautions or exercise reasonable care to warn Plaintiffs health care providers of the potential risks and serious thrombotic and cardiovascular side effects of Vioxx ingestion;

m. Defendant negligently failed to take any reasonable precautions or exercise reasonable care to warn the health care industry of the potential risks and serious thrombotic and cardiovascular side effects of Vioxx ingestion;

n. Defendant negligently failed to provide adequate post-marketing warnings or instructions after the Defendant knew or should have known of the significant risks of personal injury and death as identified herein among other serious side effects from the use of Vioxx;

o. Defendant negligently failed to warn Plaintiff that Vioxx should not be used in conjunction with any risk factors for these adverse events such as a

family history of ischemic heart disease, or risk factors for ischemic cardiovascular disease; and,

p. Defendant negligently failed to warn Plaintiff that he undertook the risk of adverse events and death relating to Vioxx as described herein.

q. Defendant negligently failed to provide warnings of the cardiovascular risks and other health risks of Vioxx which it knew or should have known subsequent to initially putting Vioxx on the market

57. Defendant's acts of negligence, as described above but not limited to these specific acts, proximately caused the Plaintiff's injuries and the occurrence in question.

WHEREFORE, Plaintiff demands compensatory damages, plus interest and costs.

COUNT II

NEGLIGENCE - SALE OF PRODUCT

58. Plaintiff re-alleges and incorporates the foregoing allegations.

59. Defendant, during some or all relevant times, manufactured, sold, marketed, and/or distributed Vioxx that was supplied to Plaintiff for use.

60. Plaintiff was exposed to and ingested this hazardous product.

61. Defendant had the duty, as product sellers, to exercise reasonable care for the safety of the Plaintiff.

62. These duties included the responsibility for the following safety and health matters relating to Vioxx:

a. the investigation of the health risks;

b. writing and publishing adequate and timely precautionary product labels and other health and safety information.

c. writing and publishing adequate and timely specifications and standards about the true risks of injury associated with the products;

d. writing and publishing adequate and timely specifications and standards about the symptoms of such injuries;

e. writing and publishing adequate and timely specifications and standards about the scope of such injuries; or

f. writing and publishing adequate and timely specifications and standards about the severity of the known risks associated with these products.

63. Defendant knew, or in the exercise of reasonable care should have known, that Vioxx would cause adverse cardiovascular effects to its consumers like the Plaintiff.

64. Defendant breached its duty of reasonable care to Plaintiff and was negligent, without regard to whether the acts were intentional, knowing, malicious or reckless.

65. Defendant's negligent acts and omissions were the direct and proximate causes of the occurrence in question and Plaintiff's injuries and damages.

WHEREFORE, Plaintiff demands compensatory damages, plus interest and costs.

COUNT III
COMMON LAW FRAUD

66. Plaintiff re-alleges and incorporates the foregoing allegations.

67. Defendant committed common law fraud against Plaintiff.

68. Defendant had a duty to disclose the risks associated with the use of Vioxx.

69. Defendant made numerous material misrepresentations about the safety and efficacy of Vioxx, with full knowledge of the falsity of these representations and/or made these misrepresentations with such utter disregard and recklessness as to whether the statements were true or false, that knowledge may be inferred.

70. Additionally, or in the alternative, Defendant failed to disclose material facts within its knowledge.

71. Additionally, or in the alternative, Defendant concealed material facts within its knowledge.

72. Defendant knew that Plaintiff was ignorant of the fact and did not have an equal opportunity to discover the truth about the dangers presented by Vioxx.

73. Defendant intended to induct consumers such as Plaintiff to take some action, among other things, to buy and ingest Vioxx, by failing to disclose the material facts.

74. Plaintiff justifiably relied on Defendant's material misrepresentations to her detriment; but for Defendant's fraud, Plaintiff would not have been exposed to Vioxx would not have suffered the injuries and occurrence in question.

WHEREFORE, Plaintiff demands compensatory damages, plus interest and costs.

COUNT IV

BREACH OF EXPRESS AND IMPLIED WARRANTIES

75. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

76. Merck, through descriptions, affirmations of fact, and promises relating to their Vioxx drugs to the FDA, prescribing physicians, and the general public, including the Plaintiff, implicitly and/or expressly, warranted that Vioxx was both safe and efficacious for its intended use.

77. Plaintiff would show that Defendant has breached its implied warranties of merchantability and fitness as set forth in Mass. Gen. Laws Ann., Ch. 106, § 2-314 – 2-318 and other applicable provisions of the Uniform Commercial Code. Plaintiff would show that Defendant Merck sold Vioxx to Plaintiff, who purchased Vioxx for the treatment of pain as prescribed by her physicians. Vioxx was unreasonably dangerous and defective as designed, manufactured and/or marketed without adequate warnings and therefore not fit for the ordinary purposes for which it was used for reasons stated herein.

78. When Defendant Merck placed Vioxx into the stream of commerce, Defendant knew of the intended uses and impliedly warranted that Vioxx, individually and/or in combination with other drugs, was of good and merchantable quality and not defective, unsafe, or unfit for the

ordinary purpose for which it was used.

79. Defendant breached its implied warranties to the Plaintiff because the Vioxx that the Plaintiff purchased or used was not of merchantable quality and was defective, unreasonably dangerous, unsafe, and not fit for the purposes for which that drug was used.

80. Plaintiff was a foreseeable and intended user of the products sold by Defendant.

81. Plaintiff, and others, reasonably and foreseeably relied upon the warranties, skill, expertise, and judgment of Defendant and their agents in assuming that the products manufactured, marketed, distributed, and sold by Defendant would be safe and fit for its intended use and would be of merchantable quality.

82. As a direct and proximate result of their breaches of implied warranties, Defendant has caused damages to Plaintiff in an amount yet to be determined.

83. Merck's breach of these warranties was a direct and proximate cause of the occurrence in question and Plaintiff's injuries and damages.

84. Likewise, Defendants is liable for breach of its express warranties. These warranties came in the form of:

a. Publicly made written and verbal assurances of the safety and efficacy of Vioxx by Merck;

b. Press releases, interviews and dissemination via the media of promotional information, for the sole purpose of which was to create an increased demand for Vioxx, which failed to warn of the risks inherent to the ingestion of Vioxx;

c. Verbal assurances made by Merck regarding Vioxx and the downplaying of any risk associated with the drug;

d. False and misleading written information, supplied by Merck, and published in the Physician's Desk Reference on an annual basis, upon which physicians were forced to rely in prescribing Vioxx during the period of Plaintiff's ingestion of Vioxx including, but not limited to, information relating the recommended duration of the use of the drugs;

e. Promotional pamphlets and brochures published and distributed by Merck and marketed directly to consumers, which contradicted the information that was set forth in the package insert and the Physician's Desk Reference; and

f. Advertisements, including but not limited to direct to consumer advertising.

85. The documents referred to above were created by and at the direction of Defendant.

86. At the time of these express warranties, Merck had knowledge of the purpose for which Vioxx was to be used and warranted it to be in all aspects safe, effective and proper for such purpose, when it was not.

87. Merck knew and had reason to know that Vioxx did not conform to these express representations in that Vioxx is neither safe nor as effective as represented, and that Vioxx produces serious adverse side effects.

88. As Merck's products were neither in conformity to the promises, descriptions or affirmations of fact made about Vioxx nor adequately contained, packaged, labeled or fit for the ordinary purpose for which these goods were sold and used.

89. Merck breached these express and implied warranties to Plaintiff in violation of the applicable provisions of the Uniform Commercial Code by:

a. manufacturing, marketing, packaging, labeling and selling Vioxx to Plaintiff in such a way that misstated the risks of injury, without warning or disclosure thereof by package or label of such risks to the Plaintiff or the prescribing physicians or pharmacist, and without modifying or excluding such express warranties;

b. manufacturing, marketing, packaging, labeling, advertising and selling Vioxx to Plaintiff, which failed to counteract the negative health effects and increased risks in a safe and permanent manner; and

c. manufacturing, marketing, packaging, labeling, advertising, promoting and selling Vioxx to Plaintiff, thereby causing the increased risk of serious physical injury and death, pain and suffering.

90. Merck possessed or should have possessed evidence that Vioxx causes serious side

effects. Nevertheless, Merck continued to market Vioxx and provided false and misleading information without regard to the safety and efficacy of Vioxx.

91. Merck's actions, as described above, were performed willfully, intentionally and with reckless disregard for the rights of Plaintiff and the public.

WHEREFORE, Plaintiff demands compensatory damages, plus interest and costs.

COUNT V

NEGLIGENT MISREPRESENTATION

92. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

93. Defendant, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and/or promotion of the product described herein, owned a duty to provide accurate and complete information regarding its products.

94. Defendant falsely represented to Plaintiff that Vioxx was safe and effective. The representations by Defendant were in fact false and in fact Vioxx was not safe for said purpose and in fact dangerous to the health of Plaintiff.

95. At the time the aforesaid representations were made, Defendant concealed from Plaintiff and others information about the propensity of Vioxx to cause great harm.

96. Defendant negligently misrepresented claims regarding the safety and efficacy of Vioxx despite the lack of information regarding same.

97. The aforesaid misrepresentations were made by Defendant with the intent to induce Plaintiff to use Vioxx to Plaintiffs detriment.

98. At the time of Defendant's misrepresentations and omissions, Plaintiff was ignorant of the falsity of these statements and reasonably believed them to be true.

99. Defendant breached its duty to Plaintiff by providing false, incomplete and/or

misleading information regarding its product. Plaintiff reasonably believed Defendant's representations and reasonably relied on the accuracy of those representations when purchasing and using Vioxx.

100. Defendant's negligent representations were a direct and proximate cause of the occurrence in question and Plaintiff's injuries and damages.

WHEREFORE, Plaintiff demands compensatory damages, plus interest and costs.

COUNT VI
FRAUDULENT MISREPRESENTATION

101. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

102. Defendant, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and promotion of Vioxx described herein, owed a duty to provide accurate and complete information regarding the products.

103. Defendant fraudulently misrepresented information regarding Vioxx including, but not limited to, the propensity to cause serious physical harm.

104. At the time of Defendant's fraudulent misrepresentations and omissions, Plaintiff was unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

105. Defendant breached its duty to the Plaintiff by providing false, incomplete and misleading information regarding Vioxx.

106. Defendant acted with deliberate intent to deceive and mislead Plaintiff.

107. Plaintiff reasonably relied upon Defendant's deceptive, inaccurate and fraudulent misrepresentations.

108. Defendant's fraudulent misrepresentations were the direct and proximate causes of the occurrence in question and Plaintiff's injuries and damages.

WHEREFORE, Plaintiff demands compensatory damages, plus interest and costs.

CAUSES OF ACTION AGAINST PFIZER

COUNT VII
NEGLIGENCE

109. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

110. Defendant Pfizer had a duty to exercise reasonable care in the manufacture, sale and/or distribution of Celebrex into the stream of commerce, including a duty to assure that the product did not cause users to suffer from unreasonable, dangerous side effects when used.

111. Defendant failed to exercise ordinary care in the manufacture, sale, testing, quality assurance, quality control, and/or distribution of Celebrex into interstate commerce in that Defendant knew or should have known that the products created a high risk of heart attack/stroke, pulmonary embolism, and organ failure due to thrombosis which can cause extraordinary suffering and death.

112. Defendant was negligent in the design, researching, developing, manufacturing, testing, advertising, warning, marketing and sale of Celebrex, in that it:

a. Failed to use due care in designing and manufacturing the products so as to avoid the aforementioned risks to individuals;

b. Failed to accompany their products with proper warnings regarding possible adverse side effects associated with the use of the products;

c. Failed to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the products;

d. Failed to provide adequate training and instruction regarding appropriate use of the products;

e. Failed to warn Plaintiff of the aforementioned risks, prior to actively encouraging the sale of the products either directly or indirectly, orally or in writing;

f. Failed to adequately test and/or warn about the reaction or interaction of the products including, without limitation, the possible adverse side effects;

g. Failed to warn that the risks associated with the products would exceed other safer alternatives; and

h. Were otherwise careless or negligent.

113. Despite the fact that Defendant knew or should have known that the products when prescribed, caused unreasonable, dangerous side effects which many users would be unable to remedy by any means, Defendant continued to market the products to consumers including Plaintiff, when there were safer alternative products.

114. Defendant knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of its failure to exercise ordinary care as described above.

115. Pfizer's negligence was a direct and proximate cause of the occurrence in question and Plaintiff's injuries and damages.

WHEREFORE, Plaintiff demands compensatory damages, plus interest and costs.

COUNT VIII
BREACH OF EXPRESS WARRANTIES

116. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

117. Defendant expressly warranted that Celebrex was safe and well accepted by patients studied.

118. Celebrex does not conform to these express representations because the products are not safe and have high levels of serious side effects, including life threatening side effects.

119. Defendant breached its express warranties to Plaintiff because the Celebrex that the Plaintiff purchased or used was unsafe and had an unacceptably high propensity for serious side effects, including life threatening side effects.

120. Pfizer's breach of express warranties was a direct and proximate cause of the occurrence in question and Plaintiff's injuries and damages.

WHEREFORE, Plaintiff demands compensatory damages, plus interest and costs.

COUNT IX
BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE

121. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

122. When Defendant placed Celebrex into the stream of commerce, Defendant knew of the intended uses and impliedly warranted that the products used, individually and/or in combination with other drugs, were of good and merchantable quality and not defective, unsafe, or unfit for the ordinary purpose for which they was used.

123. Defendant breached its implied warranties of merchantability and fitness as set forth in Mass. Gen. Laws Ann., Ch. 106, § 2-314 – 2-318 and other applicable provisions of the Uniform Commercial Code, because the Celebrex that the Plaintiff purchased or used was not of merchantable quality and was defective, unreasonably dangerous, unsafe, and not fit for the purposes for which that drug was used.

124. Plaintiff was a foreseeable and intended user of the products sold by Defendant.

125. Plaintiff, and others, reasonably and foreseeably relied upon the warranties, skill, expertise, and judgment of Defendant and their agents in assuming that the products manufactured, marketed, distributed, and sold by Defendant would be safe and fit for its intended use and would be of merchantable quality.

126. As a direct and proximate result of their breaches of implied warranties, Defendant has caused damages to Plaintiff in an amount yet to be determined.

127. Pfizer's breach of these warranties was a direct and proximate cause of the occurrence in question and Plaintiff's injuries and damages.

WHEREFORE, Plaintiff demands compensatory damages, plus interest and costs.

COUNT X
NEGLIGENT MISREPRESENTATION

128. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

129. Defendant, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and/or promotion of Celebrex, owned a duty to provide accurate and complete information regarding its products.

130. Defendant falsely represented to Plaintiff that Celebrex was safe and effective. The representations by Defendant were in fact false and in fact Celebrex was not safe for said purpose and in fact dangerous to the health of Plaintiff.

131. At the time the aforesaid representations were made, Defendant concealed from Plaintiff and others information about the propensity of Celebrex to cause great harm.

132. Defendant negligently misrepresented claims regarding the safety and efficacy of Celebrex despite the lack of information regarding same.

133. The aforesaid misrepresentations were made by Defendant with the intent to induce Plaintiff to use Celebrex to Plaintiffs detriment.

134. At the time of Defendant's misrepresentations and omissions, Plaintiff was ignorant of the falsity of these statements and reasonably believed them to be true.

135. Defendant breached its duty to Plaintiff by providing false, incomplete and/or

misleading information regarding its product. Plaintiff reasonably believed Defendant's representations and reasonably relied on the accuracy of those representations when purchasing and using Celebrex.

136. Defendant's negligent representations were a direct and proximate cause of the occurrence in question and Plaintiffs injuries and damages.

WHEREFORE, Plaintiff demands compensatory damages, plus interest and costs.

COUNT XI
FRAUDULENT MISREPRESENTATION

137. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

138. Defendant, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and promotion of Celebrex described herein, owed a duty to provide accurate and complete information regarding the products.

139. Defendant fraudulently misrepresented information regarding its products including, but not limited to, the propensity to cause serious physical harm.

140. At the time of Defendant's fraudulent misrepresentations and omissions, Plaintiff was unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

141. Defendant breached its duty to the Plaintiff by providing false, incomplete and misleading information regarding its products.

142. Defendant acted with deliberate intent to deceive and mislead Plaintiff.

143. Plaintiff reasonably relied upon Defendant's deceptive, inaccurate and fraudulent misrepresentations.

144. Defendant's fraudulent misrepresentations were the direct and proximate causes of the occurrence in question and Plaintiff's injuries and damages.

WHEREFORE, Plaintiff demands compensatory damages, plus interest and costs.

DISCOVERY RULE AND FRAUDULENT CONCEALMENT

145. The nature of Plaintiff's injuries and the relationship to Vioxx and Celebrex use were inherently undiscoverable; and consequently the discovery rule should be applied to toll the statute of limitations until Plaintiff knew or through the exercise of reasonable care and diligence should have known of the existence of potential claims against Defendants. Plaintiff did not discover and through the exercise of reasonable care and due diligence could not have discovered her injuries earlier nor could he have discovered her injuries were due to the negligent action of Defendants until the withdrawal of Vioxx from the market.

146. Because Defendants Merck and Pfizer fraudulently concealed their wrongful conduct as alleged above and Plaintiff using reasonable diligence, could not and did not discover her right of action until very recently, Defendants are estopped from asserting any and all potentially applicable statues of limitations, if any.

147. Any and all potentially applicable statues of limitations have been tolled by Merck and Pfizer's affirmative and intentional acts of fraudulent conduct, concealment, and misrepresentation, alleged above. Such acts include by are not limited to intentionally concealing and refusing to disclose the material risks associated with the use of their drugs.

148. Defendants are estopped from relying on any statutes of limitation because of its fraudulent concealment and misrepresentation alleged above. Merck and Pfizer were under a duty to disclose the risks of adverse cardiovascular events associated with the use of their drugs because this is nonpublic information over which they had exclusive control. Defendants knew this information was not readily available to Plaintiff and was relevant to Plaintiff in deciding whether to use these drugs.

149. Until very recently, Plaintiff had no knowledge that Merck and/or Pfizer engaged in the wrongdoing alleged herein. Because of the fraudulent and active concealment of the wrongdoing by Merck and Pfizer, including but not limited to deliberate efforts to give Plaintiff the materially false impression that they undertook all feasible safety precautions to reduce the risk of adverse cardiac events, Plaintiff could not have discovered the wrongdoing any time prior to this time, nor could Plaintiff have, as a practical matter, taken legally effective action given the unavailability, until very recently, of the internal memoranda and other documents (as generally described herein) as evidence in support of Plaintiffs claims.

PRAYERS FOR RELIEF

WHEREFORE, Plaintiff requests that this Court enter a judgment against the Defendants, and in favor of the Plaintiff, and to award the following relief:

a. General damages in the sum in excess of the jurisdictional minimum of this Court;

b. Compensatory damages

c. Consequential damages;

d. Pre-judgment and post-judgment interest as provided by law;

e. Costs, including, but not limited to, discretionary Court Costs of this cause, and those costs available under the law, as well as expert fees and attorney fees and expenses, and costs of this action; and

f. Such other relief as the Court deems just and proper.

XIV. JURY DEMAND

The Plaintiff demands a trial by jury.

Respectfully submitted,

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